Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2100961	06/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Golden Gate Urgent Care	750 Redwood Hwy Ste 1204, Mill Valley, CA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on 06/06/2018 (survey date), review of laboratory policies and procedures, quality control records, patient testing logs for one (1) of ten (10) randomly selected patient report from 11/16/2016 to 06/05/2018, and analyzer QC printouts/patients reports, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. On 09/07/2017 the hematology quality control (QC) sample (normal) performed on the Sysmex XP- 300 instrument was manually incorrectly transcribed into the analyzer's data report for the hematocrit (HCT) as 345.0 which exceeded the QC normal control reference range established for the instrument, also no documentation of could be retrieve that the QC data was reviewed for accurate and reliability and that corrective action was recorded for the period cited. b. The laboratory staff affirmed on 06/06/2018 13:00 (survey date) that here was no evidence that the laboratory monitored, assessed, and corrected quality control results failed to meet the criteria for acceptability. c. The laboratory testing declaration signed 06/03/2018 estimated 415 hematocrit (HCT) tests were reported annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on 06/06/2018 13:00 (survey date), review of laboratory policies and procedures, quality control records, patient testing logs for ten (10) randomly selected patient report from 11/16/2016 to 06/05/2018, and analyzer QC printouts/patients reports, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. For the period cited above there was no evidence documented that the laboratory monitored, assessed, and corrected quality control (QC) results to meet the criteria for acceptability and when indicated, correct problems identified in the analytic system. See (5783).
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on staff interviews on 06/06/2018 13:00 (survey date) and review of test procedures and ten (10) randomly selected patient test reports from 11/16/2016 to 06 /05/2018, it was determined that the laboratory failed to ensure that test reports included pertinent information required for interpretation of the hematology CBC profile (e.g., HGB, WBC, HCT, RBC, MCV, MCHC, Plt, Lym%, MXD%, Neut%, LYM#, MXD#, NEUT#, RDW-SD, RSW-CV, MPV) performed on the Sysmex XP-300 analyzer and patient population (gender/age) specific(s), if applicable. The findings included: a. Review of the laboratory's final patient test reports (medical record) showed that the laboratory failed to include pertinent information required for interpretation. There was no information provided for "normal values" and (patient population/gender/age) specific(s), if applicable noted on the patient's final test report. . b. The laboratory staff affirmed on 06/06/2018 13:00 (survey date) that the patients' final test reports failed to ensure that test reports included pertinent information required for interpretation. c. According to the laboratory testing declaration (Form LAB 144A) signed, dated by the laboratory director, and submitted by the laboratory on 06/03/2018, the laboratory performed and reported approximately 415 hematology CBC profiles testing per year.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and policies and procedures, and interview with the laboratory staff on 06/06/2018 (survey date), it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems and document all analytic systems assessment activities. The findings included: a. No documents were available to show QAs have been done following a schedule and plan. b. The laboratory staff affirmed (06/06/2018 13:00) that no records were available to show the QA been performed for the deficiencies found. (See D5791).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff, review of policies/procedures, quality control documents, instrument printouts, and ten (10) random patients reports from 06 /02/2016 to 06/05/2018, it was determined that the laboratory director failed to ensure that a quality control program was established and maintained to assure quality test results. The findings included: a. The laboratory director failed to ensure that a written quality control policy that was followed by the laboratory and corrective actions were taken and documented when quality control results failed to meet the criteria for acceptability. b. Based on review of quality control records, patient test records on 06 /06/2018 13:00 (survey date), it was determined that the laboratory director failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided. (See D5783).
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on review of the laboratory result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that reports of test results include pertinent information required for interpretation. The findings included: See D-5805